



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10286 and CMS-10325]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html).

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10286 Notice of Research Exception under the Genetic Information Nondiscrimination

CMS-10325 Disclosure and Recordkeeping Requirements for Grandfathered Health Plans
under the Affordable Care Act

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA

requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) the research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS-10286 (OMB control number: 0938-1077); *Frequency:* Occasionally; *Affected Public:* Private Sector; State, Local or Tribal governments; *Number of Respondents:* 2; *Total Annual*

Responses: 2; Total Annual Hours: 0.5. For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosure and Recordkeeping Requirements for Grandfathered Health Plans under the Affordable Care Act; *Use:* Section 1251 of the Affordable Care Act provides that certain plans and health insurance coverage in existence as of March 23, 2010, known as grandfathered health plans, are not required to comply with certain statutory provisions in the Act. The final regulations titled “Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections” (80 FR 72192, November 18, 2015) require that, to maintain its status as a grandfathered health plan, a plan must maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents that are necessary to verify, explain or clarify status as a grandfathered health plan. The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a state or federal agency official. A grandfathered health plan is also required to include a statement in any summary of benefits under the plan or health insurance coverage, that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act, and providing contact information for participants to direct questions and complaints. In addition, a grandfathered group health plan that is changing health insurance issuers is required to provide the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph §147.140(g)(1) of the final regulations are exceeded. It is also required that, for an insured group health plan (or a multiemployer plan) that is a grandfathered plan, the relevant policies, certificates, or contracts of insurance, or plan documents must disclose in a prominent and

effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year. *Form Number:* CMS-10325 (OMB control number: 0938-1093);

Frequency: Occasionally; *Affected Public:* Private Sector, State, Local or Tribal governments;

Number of Respondents: 14,669; *Total Annual Responses:* 2,651,523; *Total Annual Hours:* 40.

For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650.

Dated: January 6, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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